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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/721,881	11/27/2000	Michel L.P.M. Verhoeven	P-4566	4027

28390 7590 10/19/2004
MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER

JACKSON, SUZETTE JAMIE

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/721,881

Applicant(s)

VERHOEVEN, MICHEL L.P.M.

Examiner

Suzette J Jackson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 4-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicants Response dated 7/13/04 has been received in application serial number 09/721,881.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-2, and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. 6,110,483 in view of Elton 5,160,790. Whitbourne et al. discloses the invention as claimed comprising: A radially expandable stent comprising a wire having a substantially uniform hydrogel coating layer thereon; wherein the layer has an average dry coating thickness of about 0.01 micrometers to about 25 micrometers; and wherein the layer has a biologically active agent, a biocompatible, hydrophilic surface. See col. 1, lines 45-47; col 2, lines 6-9, 25-31, 34-35, 40, 53-67; col. 6, lines 28-58; col 7, lines 15-17 and col. 8, lines 19-21 however Whitbourne et al. does not specify that *the thickness of the coating has a standard deviation of no greater*

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than 10 percent. Elton teaches a hydrogel coating that can be applied to a stent in a uniform continuous thickness (col. 4, lines 10-14). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the coating of Whitbourne et al. and apply a uniform thickness (*with no greater than 10 percent standard deviation*) because Whitbourne et al. discloses that the coatings of the invention may be thin on the order of 2-100 microns and preferably less than about 50 microns (see col. 7, lines 15-17) and that the coating is a continuous thin layer (see col. 4, line 18).

Response to Arguments

4. Applicant's arguments filed 7/13/04 have been fully considered but they are not persuasive. Applicant contends that "*..Whitbourbe merely discloses the use of a hydrogel coating which may be thin, on the order of 1-100 microns and preferably less than about 50 microns*". It is the examiners opinion that office action is proper because in col. 20, lines 22-33 Whitbourne discloses that in a test sample the coated wire of the prior art technology had cracks, and sections between the cracks were straight; the sample coated with the Whitbourne technology had no cracks, and had a smooth, continuous arc. It would be obvious to one having ordinary skill in the art to realize that because the wire coated with hydrogel of Whitbourne is smooth with no cracks that there can be a standard deviation of no greater than 10 percent (which is interpreted as anything from zero percent up to 10 percent. It also would have been obvious because

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Whitbourne addresses the same problems that applicant has stated were common in the past and that is to prevent lack of coating uniformity, surface roughness and undesirable drug release properties.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

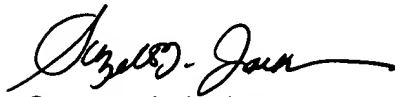
6. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzette J. Jackson whose work schedule is Monday-Friday 9-6:30 off every other Friday and whose telephone number is 703-308-6516.

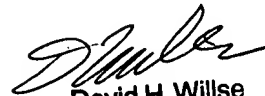
7. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306.

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8. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Suzette J. Jackson
14 October 2004



David H. Willse
Primary Examiner